IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Amar Lulla, *et al.*	§	
		§	Group Art Unit: 1618
Serial No.:	10/574,135	§	
		§	Examiner: Nissa M. Westerberg
Filed:	October 18, 2006	§	
		§	Confirmation No.: 8688
For:	PHARMACEUTICAL FORMULATION WITH IMPROVED STABILITY	§	

DECLARATION UNDER 37 CFR § 1.132

I, Geena Malhotra, hereby declare and say that:

1. I am a co-inventor of the invention claimed in the above-identified patent application.

2. I have carried out experiments to assess the level of impurities in the compositions described and claimed in the current patent application. The results of these experiments are presented in Tables 1 and 2 of Exhibit A.

3. Referring to Exhibit A, I have demonstrated the compositions described and claimed in the current patent application have a high degree of stability as evidenced by the low level of impurities formed over storage for up to 24 months under the described conditions. This is further supported by the data presented in Exhibit A that demonstrates there is no significant increase in the water content of the formulation over the time period observed.

4. Further, I believe the processes of the cited references, namely WO 02/03963 to Jasprova; WO 02/00204 to Flas-Ner-Barak et al.; or WO 95/29679 to Katdare et al.; do not yield a product having the claimed intragranular phase and that the stability of the presently claimed formulations is at least in part attributable to the presence of the intragranular phase.

5. I, Geena Malhotra, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

09/11/09
Date

Geena Malhotra

Exhibit A

Table 1

Storage Conditions: Temperature 40 °C ± 2 °C and 75% ± 5% relative humidity

Testing Intervals	Total Impurities NMT[1] 0.50%	Water Content [NMT 8% w/w]
Initial	Below LQQ [2]	2.9
4 weeks	Below LQQ	2.7
8 weeks	Below LQQ	2.5
12 weeks	0.08	2.6

Table 2

Storage Conditions: Temperature 25 °C ± 2 °C and 60% ± 5% relative humidity

Testing Intervals	Total Impurities NMT[1] 0.50%	Water Content [NMT 6.5% w/w]
Initial	Below LQQ [2]	2.9
12 weeks	Below LQQ	2.6
6 months	Below LQQ	3.1
9 months	0.06	2.9
12 months	0.05	3.0
18 months	0.05	3.0
24 months	0.06	3.2

[1] NMT= not more than

[2]LQQ [Limit of Quantification]: limit below which the amount of drug/active or any substance cannot be quantified